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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,195	07/31/2001	Gloria DeCarlo Massaro	17293DIV(HL)	4830

7590
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09/15/2003

EXAMINER

SEAMAN, D MARGARET M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 09/15/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/919,195	Applicant(s) MASSARO ET AL.	
	Examiner D. Margaret Seaman	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

This application was filed 31 July 2001 and is a DIV of 09/548,897 (13 April 2000) which claims benefit of 60/129,213). RCE papers (paper #8) was filed 10 February 2003. Claims 13-28 are before the Examiner.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 13-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims do not meet the requirements for adequate written description of the claimed invention because the scope of the claims is unknown due to the structure limitations not being specifically disclosed. There is no description of the identifying characteristics for recognizing that a candidate compound antagonizes RAR β and has specific RAR modulating activity and such antagonist is not specific to at least one other RAR receptor subtype. There are no structural

characteristics of such an antagonist provided, nor is there any indication that applicant had possession of any antagonist. Further, the claimed method required treatment of an unspecified disease. Because one skilled in the art would conclude that the inventors were not in possession of the claimed invention, the claim fails to comply with the written description requirement.

3. Claims 13-28 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As stated previously, the claimed invention is drawn to compositions that have RAR β antagonist having specific RAR modulating activity and a method of treating using such compositions. However, the only compounds that are enabled by the instant specification have already been patented. No other compounds have been suggested or enabled by the instant specification. It is not seen where the instant specification enables the ordinary artisan to make or use the instant invention without undue experimentation.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in

the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

1) The breadth of the claims: The claims are drawn to any and all known and unknown compounds that have RAR antagonist having specific RAR modulating activity.

3) The state of the prior art: The prior art has specific compounds that have utility as RAR α , β , and γ antagonist activities either specifically or generally to the RAR α , β , and γ . However, the prior art starts with a compound and determines that the compound has certain activity. The prior art does not specify an activity and then searches any and all known and unknown compounds to find one or more that fit the activity.

5) The level of predictability in the art: The level of predictability in the art is unknown due to the prior art starting with a core of compounds and not with a core activity.

6) The amount of direction provided by the inventor: The inventor provides no direction beyond compounds already known (and patented) that have the RAR antagonist activity. There is no guidance as to where to go from the specific compound disclosed on page 16 of the instant specification. The specification provides only a method of testing, not a direction of which to test.

7) The existence of working examples: There is one compound shown on page 16 of the specification. There are no other working examples.

8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: The amount of experimentation needed to make/use the instant invention is unexpected. The test available only gives the test to which a compound can be shown to either have or not have the needed activity. The test does not provide a direction to which the ordinary skilled artisan should proceed other than any and all known and unknown compounds.

Taking the above factors into consideration, it is not seen where the instant specification enables the ordinary artisan to make/use the instant invention without undue experimentation.

The specification does not provide any guidance with exception to the compounds of the parent patent, with respect to any working examples. One skilled in the art would first have to determine the activity of the receptor in order to develop the claimed invention. If the ordinary artisan doesn't know the structure of what compound meets the particulars of the instant claims, then the ordinary artisan doesn't know how to make the compounds that fulfill the instant claims. Furthermore, no information is presented as to how the undisclosed antagonist compound would have been administered to treat an unspecified disease. Thus, the skilled artisan would not have been able to practice the steps required by the claimed invention.

Applicants argue that a new method of using an old compound is patentable. However, applicants do not specify any group of compounds that would meet the instant claims. The only way to determine if any compound (including aspirin) would

fulfill the instant claims is to test the compound to see if it fits within the parameters of the instant claims. This would mean that every compound that exists and any compound that does not yet exist fall within the scope of the instant claims. The only thing one artisan must do is to test the compound to see if it fits within the instant parameters. That is unexpected experimentation. Claims limited to the Markush scope of the parent Patent #6,303,648, could be considered allowable if a proper terminal disclaimer is presented.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The rejection of claims 13-28 under 35 U.S.C. 102(b) as being anticipated by Ghaffari, Cong, Xu, Wu, Cao, Song and Yu, is upheld.

As stated previously, Ghaffari discloses compounds that RAR modulation in the lung. Cong discloses RAR modulation in its role in the development of the lung. Xu discloses modulation of RAR for lung problems. Wu discloses RAR modulation in the lung. Cao discloses RAR modulation in the lung. Song discloses RAR modulation in


the lung. Yu teaches RAR modulation and lungs. These all teach RAR modulation and lung tissues. These would inherently do the same as is instantly claimed.

Applicant argues that the reference must contain each and every limitation of the instant claims. The prior art teaches a method for treating the same conditions as is instantly claimed. Due to this, the prior art inherently must have the same activities as instantly claimed. The rejection is upheld.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Margaret Seaman whose telephone number is 703-308-4528. The examiner can normally be reached on 630am-4pm, First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


D. Margaret Seaman
Primary Examiner
Art Unit 1625

dms